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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,643

04/04/2006

Xiong Chen

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EXAMINER

HOBBS, LISA JOE

ART UNIT

PAPER NUMBER

1657

NOTIFICATION DATE

DELIVERY MODE

07/01/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/574,643	Applicant(s) CHEN ET AL.
	Examiner Lisa J. Hobbs	Art Unit 1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04 April 2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Status

Claims 1-13 are active in the case.

Information Disclosure Statement

The information disclosure statement(s) (IDS) submitted on 04 April 2006 is/are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 4, 7, 10, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by DiGiorgio et al. (US 5,804,402). DiGiorgio et al. teach a reagent for the determination of an analyte concentration in a patient wherein the degree of oxidation of a coenzyme is measured, characterized in that said reagent is stabilized against oxidation by a coenzyme reduction system comprising an enzyme and a substrate pair selected so as to enable continuous regeneration of said coenzyme throughout storage of said reagent, said enzyme having incomplete specificity for said substrate such that there is no loss in functionality of the reagent in the determination of analyte concentration throughout at least 6-8 months of storage of said reagent at 2 °C - 8 °C

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(claim 1). They teach a single vial, using glucose-6-phosphate dehydrogenase/D-glucose as the enzyme/substrate pair, and analytes of aspartate transaminase, alanine treansaminase, and blood urea (claims 2, 5, 8-11. etc.) which anticipate the claims as recited.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiGiorgi et al. (US 5,804,402), DiGiorgio et al. (5,705,356) and Cozzette (US 6306594). As discussed above, in the '402 patent, DiGiorgio et al. teach a reagent for the determination of an analyte concentration in a patient wherein the degree of oxidation of a coenzyme is measured, characterized in that said reagent is stabilized against oxidation by a coenzyme reduction system comprising an enzyme and a substrate pair selected so as to enable continuous regeneration of said coenzyme throughout storage of said reagent, said enzyme having incomplete specificity for said substrate such that there is no loss in functionality of the reagent in the determination of analyte concentration throughout at least 6-8 months of storage of said reagent at 2 °C -8 °C. They do not teach the specific concentrations recited in the dependent claims. DiGiorgio et al. teach additional information in the '356 patent, comprising testing to determine the proper regeneration levels of enzyme/substrate (col. 10, lines 16-46).

Cozzette et al. teach microfabricated biosensors, methods and materials for the mass production thereof, and their use in the determination of the presence and/or concentration of a variety of selected analyte species. In particular, the integrated biosensors of the present invention may be manufactured by a process which allows the incorporation of a variety of bioactive molecules, which bioactive molecules provide the basis of the analytical technique, through the use of materials which are compatible with the bioactive molecules and which materials have been especially adapted for that purpose. The integrated biosensors of the instant invention are also fully compatible with undiluted biological fluids and may be utilized in a wide range of medical, as well as nonmedical, applications.

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They also teach electrochemical assay procedures useful in determining the presence and/or concentration of biological species (analytes) of interest and the use of a non-electroactive substrate that does not undergo detectable oxidation or reduction at an electrode's operating potential, but which substrate undergoes a reaction with a substrate converter which gives rise to changes in the concentration of detectable electroactive species, these changes are measured and related to the concentration of the biological species of interest (col. 1, lines 19-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of DiGiorgio et al. ('402 and '356) and Cozzette et al. in order to achieve the invention as claimed. The art teaches that it is well known to fabricate sensors that measure the concentration of an analyte of choice, using an enzyme/substrate pair of choice, and choosing a regenerating system so that the sensor is able to perform multiple measurements. One of skill would be able to use the teachings to arrive at the levels of reagent recited through simple experimentation, as outlined by DiGiorgio et al. and Cozzette et al. One would have a reasonable expectation of success since the use of sensors such as those recited in the cited art and other well-known examples such as BUN/creatinine sensors is known to those of skill.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday to Friday, 8:00 a.m. to 4:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh